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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/054,889	01/25/2002	Alfred Schaufler	2002-0094A	5466
513	7590	05/18/2004		
WENDEROTH, LIND & PONACK, L.L.P.				
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SUITE 800				
WASHINGTON, DC 20006-1021				
			EXAMINER	
			MICHENER, JENNIFER KOLB	
			ART UNIT	PAPER NUMBER
			1762	

DATE MAILED: 05/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/054,889

Applicant(s)

SCHAUFLE, ALFRED

Examiner

Jennifer K Michener

Art Unit

1762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-67 is/are pending in the application.
- 4a) Of the above claim(s) 1-20 and 57-67 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 21-56 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
  - 2) ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 3/1/04.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

***Information Disclosure Statement***

1. The information disclosure statement (IDS) submitted 3/1/2004 has been considered by the examiner.

***Claim Rejections - 35 USC § 112***

2. The rejection of claims 21-40 under 35 U.S.C. 112, second paragraph, has been withdrawn based on Applicant's arguments and submissions.

***Claim Rejections - 35 USC § 103***

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Claims 21-24, 26-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zimmerman US Pat. 4,453,939.  
Examiner maintains the rejection.
5. Claims 25 and 42-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zimmerman in view of Cioca et al. (3,939,831) and Koken Co. (3/7/1995 unexamined publication).  
Examiner maintains the rejection.

***Response to Arguments***

6. Applicant's arguments filed 3/1/2004 have been fully considered but they are not persuasive.

Applicant states that the inventors have realized that fibrinogen and thrombin particles with a mean diameter between 25-100  $\mu\text{m}$  confer low abrasion when applied to a collagen carrier and argues that the references cited by Examiner fail to teach such a diameter or that certain particle sizes are beneficial with respect to abrasion characteristics. Applicant further argues that Examiner has used hindsight, instead of evidence on the record, to reason that particle size determines surface area and thus reactivity. Lastly, Applicant argues that the prior art does not recognize particle size as a variable which achieves a recognized result, such as abrasion characteristics, and thus disagrees with Examiner's assessment that diameter is a cause-effective variable that an ordinary artisan would optimize.

Examiner has considered Applicant's arguments and has reviewed the cited sections of the specification which discuss abrasion characteristics. However, the specification does not state that particle size enhances abrasion characteristics. Applicant's specification is not commensurate in scope with the arguments made because the specification does not link superior abrasion characteristics to the claimed particle range. If Applicant were to submit a declaration outlining the unexpected results obtained by using the claimed particle range, Examiner would reconsider the Zimmerman rejection.

Regarding arguments that the reference does not discuss the recognized benefit of enhanced abrasion characteristics from the use of the claimed specific particle sizes, Examiner notes that the claim does not require any specific or quantitative benefit.

Regarding arguments that Examiner has used hindsight, instead of evidence of record, to argue that particle size determines surface area and thus reactivity, Examiner disagrees. For a given volume or weight of a substance, the particle size of a particle is inherently related to surface area, as known by one of ordinary skill in the art to be inherent, and not requiring the use of hindsight. The smaller the particle size of a substance, on a weight or volume basis, the greater the relative surface area. The greater the surface area, on a weight or volume basis, the faster a given reaction can occur between two chemical substances. If Applicant disagrees with these inherency statements he should so state on the record.

Furthermore, Examiner's comments in the previous office action regarding surface area and reactivity were merely to show that particle size would have been known as a cause-effective variable. In addition, particle size affects the degree to which the particles may be dissolved in a solution. Particle size would have been known to be a cause-effective variable to an ordinary artisan creating a solution for coating, as outlined in the previous office action. In fact, Zimmerman's teaching of "fine particles" demonstrates the need to control the size of particles. Therefore, Examiner maintains that she has established particle size of a solute to be a cause-effective variable. In which case, as outlined in the previous office action, it is well settled that determination

of optimum values of cause effective variables such as these process parameters is within the skill of one practicing in the art. *In re Boesch*, 205 USPQ 215 (CCPA 1980). In the absence of a showing of criticality, such as in the form of a declaration, it would have been obvious to optimize a cause-effective variable, such as particle size.

### ***Conclusion***

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

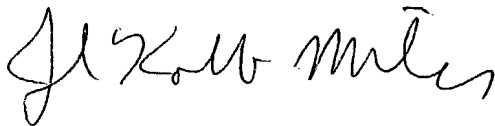
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kolb Michener whose telephone number is 571-272-1424. The examiner can normally be reached on Monday through Thursday and alternate Fridays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shrive P. Beck can be reached on 571-272-1415. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

A handwritten signature in cursive script, reading "Jennifer Kolb Michener".

Jennifer Kolb Michener  
Patent Examiner  
Technology Center 1700  
May 12, 2004